

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bosch et al.
Title: DRY POWDER AEROSOLS OF
NANOPARTICULATE DRUGS
Appl. No.: 09/190,138
Filing Date: 11/12/1998
Patent No.: 7,521,068 B2
Grant Date: 4/21/2009
Examiner: James Henry Alstrum Acevedo
Art Unit: 1616
Confirmation 6300
Number:

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT
UNDER 37 C.F.R. §1.705

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants respectfully request reconsideration of the Patent Term Adjustment (PTA) determined for the captioned patent, which issued on 4/21/2009 as U.S. Patent No. 7,521,068 B2.

The Patent Office determined that the patent was entitled to 1095 days of PTA. Applicants believe that this PTA determination was made in accordance with the “Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. §154(b)(2)(A)” published at 69 Fed. Reg. 34238 (Jun. 21, 2004). Under that interpretation of the PTA statute, any PTO delay under 35 U.S.C. § 154(b)(1)(A) is deemed to overlap with any 3-year maximum pendency delay under 35 U.S.C. § 154(b)(1)(B), and so, as a practical effect, PTA may be awarded under §154(b)(1)(A) or §154(b)(1)(B), but not both.

On September 30, 2008, the United States District Court for the District of Columbia issued a decision finding that the U.S. Patent and Trademark Office's interpretation of the PTA statute is incorrect. *Wyeth v. Dudas*, Civ. Action No. 07-1492 (JR) (Sep. 30, 2008). The court determined that, under the correct interpretation of the PTA statute, periods of "overlap" are limited to "periods of time . . . [that] occur on the same day." *Wyeth*, slip op. at 8. Thus, a PTO delay under §154(b)(1)(A) overlaps with a delay under §154(b)(1)(B) only if the delays "occur on the same day." *Id.*

Applicants have recalculated PTA for the captioned patent under the court's interpretation of the PTA statute, and have determined that the patent is entitled to 1247 days PTA, as shown on the attached sheet, which shows the relevant delays under 37 CFR §1.702(a) and (b), and under 37 CFR §1.703(a) and (b).

The attached sheet details the circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in § 1.704.

| | |
|-------------------------------------------------------------------|-----------|
| (a) Total of non-overlapping PTO delay under §154(b)(1)(A) & (B): | 1523 days |
| (b) Total Applicant delay: | 276 days |
| Final PTA Determination: | 1247 days |

Applicants therefore respectfully request that the patent be accorded 1247 days PTA.

The patent is not subject to a terminal disclaimer.

Applicants would also like to point out that on December 18, 2008, the Examiner requested that Applicants delete the illustrations on pages 15, 17, and 21 of the specification and provide drawings/figures for these illustrations. At the Examiner's request, Applicants provided along with the Issue Fee payment on December 22, 2008, three (3) sheets of drawings. Therefore, Applicants should not be charged 120 days of PTA as indicated in the U.S. PTO's PTA calculation because this was done at the Examiner's request.

Payment of the requisite fee is submitted herewith. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

However, because these PTA errors are due to a Patent Office errors in interpreting and applying the PTA statute, a refund of the fee is respectfully requested.

Applicants request further that a decision on this request be **deferred or delayed** until a final decision has been rendered in *Wyeth v. Dudas*, which is now on appeal at the U.S. Court of Appeals for the Federal Circuit, under Federal Circuit Docket No. 2009-1120.

Respectfully submitted,

Date: June 19, 2009

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Patent Term Adjustment Calculation System

Add a new event to this case

Docket Number: 029318-0109
 Application Number: 09/190138
 Patent Number: N/A

| | Event Description | Event Date | Days from Filing | PTO Days | Applicant Days |
|-------------|----------------------------------------------------------|------------|------------------|----------|----------------|
| Edit Delete | Continued Prosecution Application | 06/05/2001 | 0 | | |
| Edit Delete | Non-Final Office Action | 08/27/2001 | 83 | | |
| Edit Delete | Non-Final Office Action Rsp. Rcv'd at PTO | 11/27/2001 | 175 | | |
| Edit Delete | Final Office Action | 02/11/2002 | 251 | | |
| | Final Office Action + 3 months | 05/11/2002 | 340 | | |
| Edit Delete | Final Office Action Response Received at PTO | 07/11/2002 | 401 | | |
| Edit Delete | Notice of Appeal Received at PTO | 08/12/2002 | 433 | | 93 |
| Edit Delete | Advisory Action | 08/15/2002 | 436 | | |
| Edit Delete | Request For Continued Examination | 10/15/2002 | 497 | | |
| Edit Delete | Non-Final Office Action | 12/24/2002 | 567 | | |
| | Non-Final Office Action + 3 months | 03/24/2003 | 657 | | |
| Edit Delete | Non-Final Office Action Rsp. Rcv'd at PTO | 06/24/2003 | 749 | | 92 |
| | Non-Final Office Action Rsp. Rcv'd at PTO + 4 mo | 10/24/2003 | 871 | | |
| | CLOSE WINDOW ALL CASES SELECT CASE | | | | |
| Edit Delete | Final Office Action | 01/14/2004 | 953 | 82 | |
| | Final Office Action + 3 months | 04/14/2004 | 1,044 | | |
| Edit Delete | Final Office Action Response Received at PTO | 05/14/2004 | 1,074 | | |
| Edit Delete | Notice of Appeal Received at PTO | 07/14/2004 | 1,135 | | 91 |
| Edit Delete | Advisory Action | 07/22/2004 | 1,143 | | |
| Edit Delete | Appeal Brief Received at PTO | 10/13/2004 | 1,226 | | |
| | Appeal Brief Filed + 4 months | 02/13/2005 | 1,349 | | |
| Edit Delete | Examiner's Answer Mailed | 05/26/2006 | 1,816 | (467) | |
| Edit Delete | Reply Brief Received at PTO | 07/25/2006 | 1,876 | | |
| Edit Delete | Examiner's Answer Mailed | 09/27/2006 | 1,940 | | |
| Edit Delete | Appeal Decided by Appeal Board; Some Rejections Reversed | 06/23/2008 | 2,575 | 1441 | |
| Edit Delete | Notice of Allowance | 09/24/2008 | 2,668 | | |
| Edit Delete | Issue Fee Paid | 12/22/2008 | 2,757 | | |

Edit Delete

Patent Grant Date

04/21/2009

2,877

Totals:

1,523

276

PTA:

1,247

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